UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ALL CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO AMEND FIRST AMENDED MASTER LONG FORM COMPLAINT AND JURY DEMAND AND AMENDED MASTER SHORT FORM COMPLAINT

Defendants Ethicon, Inc. and Johnson & Johnson ("Defendants") hereby oppose in part Plaintiffs' Motion to Amend Master Long Form Complaint and Jury Demand and Amended Master Short Form Complaint [Doc. 886]. Defendants do not oppose Plaintiffs' request to add greater specificity in certain counts, to remove Ethicon LLC, and to add Cook as a potential defendant on the Short-Form Complaint. Defendants' sole objection is the addition of a "negligent training" count to the master pleadings. There is no duty to train physicians, and, in any event, Plaintiffs' proposed new count is merely a restatement of their negligence and failure to warn claims. Accordingly, Plaintiffs' attempt to amend is futile and must be denied.

BACKGROUND

These proposed amendments constitute Plaintiffs' second attempt to amend their master pleadings since they were first entered over a year ago. The Master and Short Form Complaints were entered in this case on August 22, 2012. *See* PTO # 12. Plaintiffs sought to amend the

Complaint soon thereafter to set forth additional allegations of jurisdiction and venue which were unintentionally omitted, to which Defendants had no objection. *See* PTO # 14 (Aug. 31, 2012).

Even though the Amended Master Complaint has been in place for more than a year, Plaintiffs now seek to amend the Master Complaint to add a new count. Plaintiffs request to add "Count XIX, Negligent Training" to the master pleadings. [Doc. 886]. In addition, Plaintiffs request to add greater specificity to their fraud claims. *Id.* They also seek to exclude Defendant Ethicon LLC from the master pleadings and to add Cook as a Defendant on the Short-Form Complaint. *Id.*

Finally, Defendants note that Plaintiffs' proposed Second Amended Master Long Form Complaint and Jury Demand [Doc. 886-1] omits the additional jurisdictional and venue allegations that were added with the filing of the First Amended Master Long Form Complaint and Jury Demand (PTO # 14). Defendants presume this omission was in error and request that the Court order Plaintiffs to submit a revised proposed Second Amended Master Long Form Complaint before ruling on Plaintiffs' Motion to Amend.

ARGUMENT

Federal Rule of Civil Procedure 15(a) provides that leave to amend a pleading "shall be freely given when justice so requires." FED. R. CIV. P. 15(a). The ability to amend is not unfettered, however. Rather, leave to amend may be denied "when the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would be futile." *Johnson v. Oroweat Foods Co*., 785 F.2d 503, 509 (4th Cir.1986). Whether to permit amendment is committed to the discretion of the trial court, though "outright refusal to grant the leave without any justifying reason appearing" does constitute an abuse of discretion. *Forman v. Davis*, 371 U.S. 178, 182 (1962); *see also Glaser v. Enzo Biochem, Inc*.,

126 F. App'x 593, 602 (4th Cir. 2005) (applying *Foman* and concluding that "the district court did not abuse its discretion in ruling that the plaintiffs' 'many opportunities . . . to present their claim' warranted denial of the motion to amend").

A. The Proposed Amendment Is Futile Because There Is No Independent Duty to Train Physicians.

An amendment is considered futile where "clearly insufficient or frivolous on its face." *Johnson*, 785 F.2d at 510. Plaintiffs' proposed amendment adding a negligent training claim is futile because there is no such duty to train on the part of a medical device manufacturer.

It is well-settled that medical device manufacturers are not engaged in the practice of medicine. The practice of medicine is highly-regulated, both by governmental entities through the requirement of licensure, and by the profession itself through accreditation of medical schools, board certification requirements, and special requirements for the practice of recognized specialties. With their proposed amendment, Plaintiffs seek to establish an independent claim essentially holding medical device manufacturers responsible for physicians' practice of medicine. *Cf. Hall v. Horn Medical, LLC*, 2012 U.S. Dist. LEXIS 68482, 2012 WL 1752546, at *3 (E.D. La. 2012) (finding it "patently unreasonable" for a "seasoned neurosurgeon . . . to rely on a sales representative's opinion about the type of procedure that should be employed in operating on a patient's spine.").

Courts have specifically rejected the notion that a manufacturer's duty to warn also requires a duty to train. For instance in *Glorvigen v. Cirrus Design Corp.*, 816 N.W.2d 572, 582 (Minn. 2012), the Minnesota Supreme Court observed that "[t]he duty to warn has never before required a suppler or manufacturer to provide training, only accurate and thorough instructions on the safe use of the product." The court further stated that "[t]here is no duty for suppliers or

manufacturers to *train* users in the safe use of their product. Indeed, imposing a duty to train would be wholly unprecedented." *Id.* at 583 (emphasis in original).

There particularly is no duty to train in instances, such as the present case, in which the learned intermediary doctrine applies and the product is sold to a sophisticated professional. In that situation, the manufacture has neither the duty nor the ability to monitor the professional's subsequent performance. In *Brown v. Drake-Willock Int'l, Ltd*., 530 N.W.2d 510, 515 (Mich. Ct. App. 1995), for instance, the court noted that, under Michigan law, "[a] seller or manufacturer should be able to presume mastery of basic operations by experts or skilled professionals in an industry, and should not owe a duty to warn or instruct such persons on how to perform basic operations in their industry." (emphasis added); *see also Rounds v. Genzyme Corp.*, 440 F. App'x 753, 756 (11th Cir. Sept. 8, 2011) (rejecting the plaintiffs' attempt to "circumvent the learned intermediary doctrine by characterizing the issue as one of training rather than warning" and noting that "[a]s a matter of law, [the defendant medical product manufacturer] discharged its duty to advise [plaintiffs' physician] of the risks associated with [the product] by providing clear, unambiguous information about these risks in the … package insert"); *Sons v. Medtronic Inc.*, 815 F. Supp. 2d 776, 783 (W.D. La. 2013) (finding that, even if the plaintiff's failure to train/instruct claims were not preempted, the claims should be dismissed because the defendant medical device manufacturer may not "intrude" into the practice of medicine by instructing physicians as to how to handle their patients).

By casting the negligent training claim as a separate, independent cause of action, Plaintiffs seek an unprecedented extension of the law whereby medical device manufacturers are responsible for every aspect of a physician's care of a patient. For instance, Plaintiffs allege that the *manufacturer* breached a duty by failing to train physicians as to which procedures to select

for their patients, by failing to train as to the techniques the physician should use to perform the procedure, and by failing to train physicians as to how to perform mesh removal procedures. [Doc. 886-1, ¶¶ 260(a), (c), (d), and (j)]. If Plaintiffs' argument were successful, then an injured party could very easily by analogy have a claim against a medical school for improperly training a physician who has caused her harm. This may sound preposterous, but there is, analytically, no difference. Such a claim of "educational malpractice" brought by a third party has been repeatedly rejected by various courts.[1]

Finally, even if such a claim were recognized under state law, to the extent it seeks to impose requirements related to safety and effectiveness different from those imposed by the FDA, it is preempted by the federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.* *See Gomez v. St. Judge Med. Daig Div. Inc.*, 442 F.3d 919, 928-33 (5th Cir. 2006) (finding that state law claims against a medical device manufacturer, including a claim for alleged failure to train medical personnel, were preempted by federal law); *Sons v. Medtronic Inc.*, 815 F. Supp. 2d 776, 783 (W.D. La. 2013) (finding that plaintiff's claim that medical device manufacturer negligently failed to train healthcare providers was preempted by federal law).

B. Plaintiffs' Proposed Count XIX Is Merely a Recast Failure to Warn / Negligence Claim.

Upon review of the proposed Count XIX [Doc. 886-1, p. 70-73], it is plain that the purported "negligent training" claim is nothing more than a repurposed failure to warn or

[1] *See Moss Rehab v. White*, 692 A.2d 902 (De. 1997) (rejecting third-party claim against driving school); *Waugh v. Morgan Stanley & Co.*, 966 N.E.2d 540 (Ill. App. 2012) (rejecting third-party claim against flight training school); *Dallas Airmotive, Inc. v. FlightSafety Int'l, Inc.*, 277 S.W.3d 696, 700 (Mo. Ct. App. 2008) (same); *Sheesley v. Cessna Aircraft Co.*, 2006 DSD 6; 2006 U.S. Dist. LEXIS 27133 (D.S.D. April 20, 2006) (same); *Moore v. Vanderloo*, 386 N.W.2d 108 (Iowa 1986) (rejecting third-party claim against chiropractic college); *Glorvigen v. Cirrus Design Corp.*, 796 N.W.2d 541, 552 (Minn. Ct. App. 2011) (rejecting claim against airplane manufacturer arising from "transition training" it offered to experienced pilots on flying a new or unfamiliar plane).

negligence claim. Plaintiffs' alleged breaches of duty are "failing to use reasonable care in training, educating and/or instructing physicians" about various things, including: "the risks associated with the Products," "pore size," "that Defendants had done no premarket testing," "the possibility of excessive mesh contraction," "the possibility for Product degradation," and "the possibility of permanent vaginal or rectal nerve damage." *Id.* These allegations are repetitive of the failure to warn claim, where Plaintiffs also allege that Defendants "failed to properly and adequately warn and instruct the Plaintiffs and their health care providers" of various alleged risks of the products. [Doc. 886-1, ¶¶ 101-08]. The allegations are also repetitive of the negligence claim, where Plaintiffs allege that Defendants "breached their duty of care . . . in the design, manufacture, labeling, warning, instruction, training, selling, marketing, and distribution of the Pelvic Mesh Products." [Doc. 886-1, ¶ 90].

A requested amendment is considered futile where it is merely "restating the same facts using different language [or] reasserting claims previously determined." *Garcia v. City of Chicago*, 24 F.3d 966, 970 (7th Cir. 1994). Plaintiffs' attempts to recast what are essentially negligence and failure to warn claims as a separate, independent count for "Negligent Training" should therefore be rejected.

CONCLUSION

Plaintiffs' request to add an independent negligent training claim is futile. It is without precedent and constitutes an attempt by Plaintiffs to recast their failure to warn and negligence claims, which are already included in the master pleadings. Accordingly, as to the request to add the negligent training count, Plaintiffs' motion to amend should be denied. Defendants do not oppose the remainder of Plaintiffs' motion to amend.

Dated: November 6, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 6, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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